

5 Principles of Operation

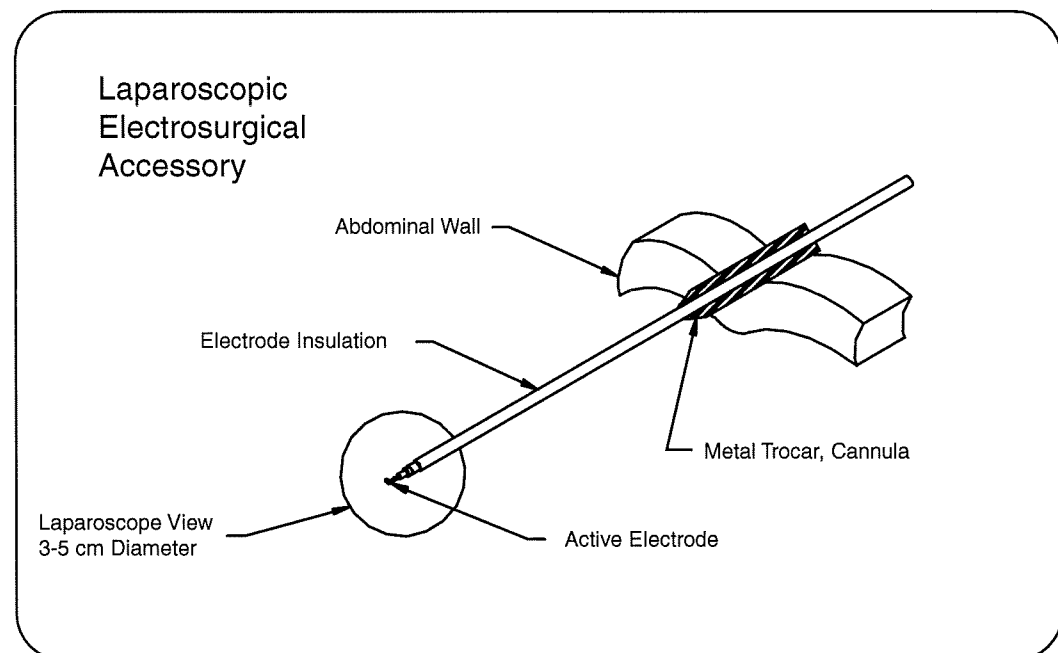
The AEM Monitor is divided into two separate functional parts: the AEM Monitor portion and the Endpoint Monitor portion. The implementation for each of these functions is independent of the other, with the exception of the power supply and enclosure.

Theory of Operation - AEM (monopolar)

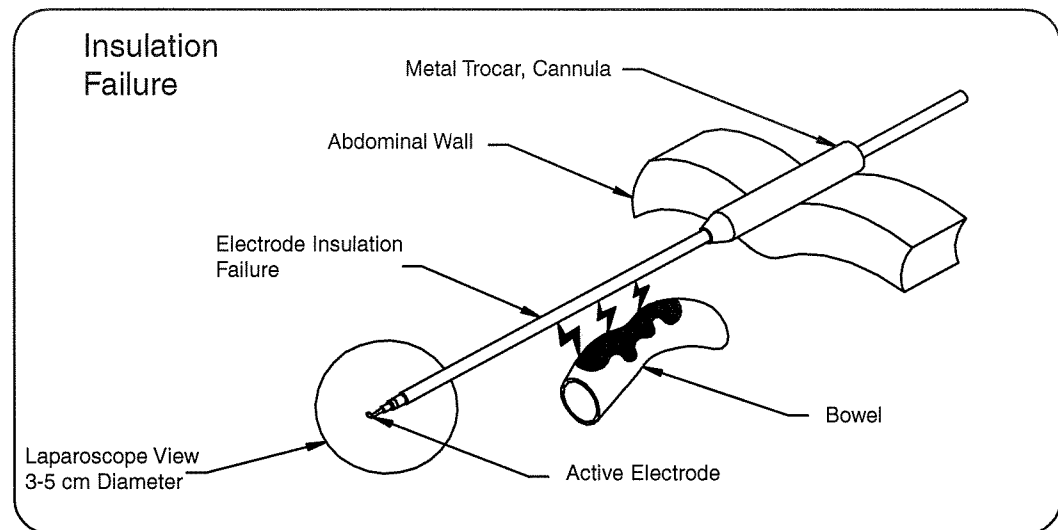
The AEM Monitoring System enhances safety by detecting insulation breakdowns and blocking stray currents that may not be detected by the surgeon during the use of electrosurgery in laparoscopic procedures. Indicators identify "Set up" and "Operative" alarms so that the proper corrective action can be taken.

During laparoscopy, monopolar electrosurgery has safety and performance issues that differ from those of open procedures.

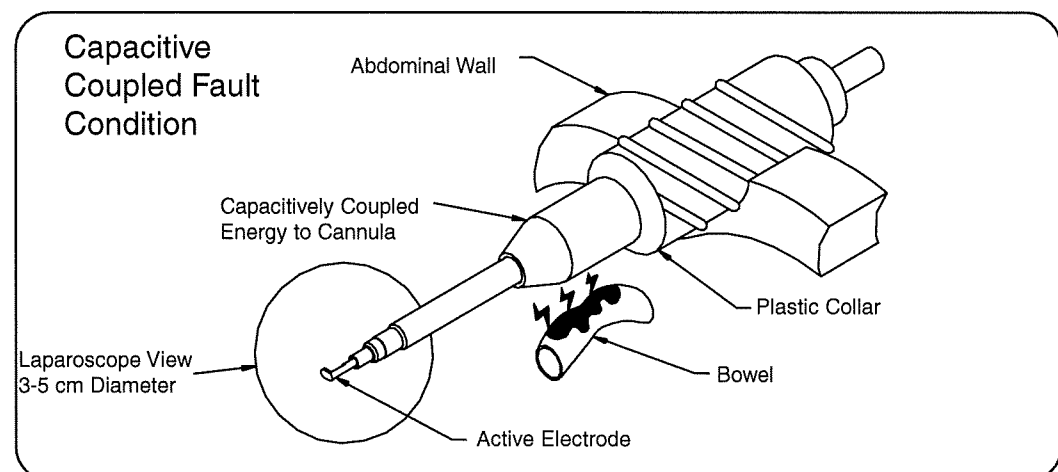
The safety of the patient depends, in part, on the quality of electrical insulation on the extended electrodes, and the amount of current which is conducted through the insulation due to capacitance. These potential electrical problems are compounded by the fact that only a small portion of the total length of the insulation may be viewed by the surgical team.

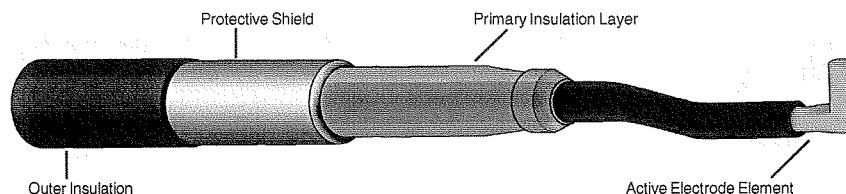


Electrosurgical equipment produces high voltage radio-frequency energy. These high voltages require insulation on the electrodes to eliminate the flow of current except at the tip. Normal wear and tear of the instruments may degrade the insulation, and such defects may be outside of the normal field of view. Consequently, a failure capable of causing harm may go unnoticed.



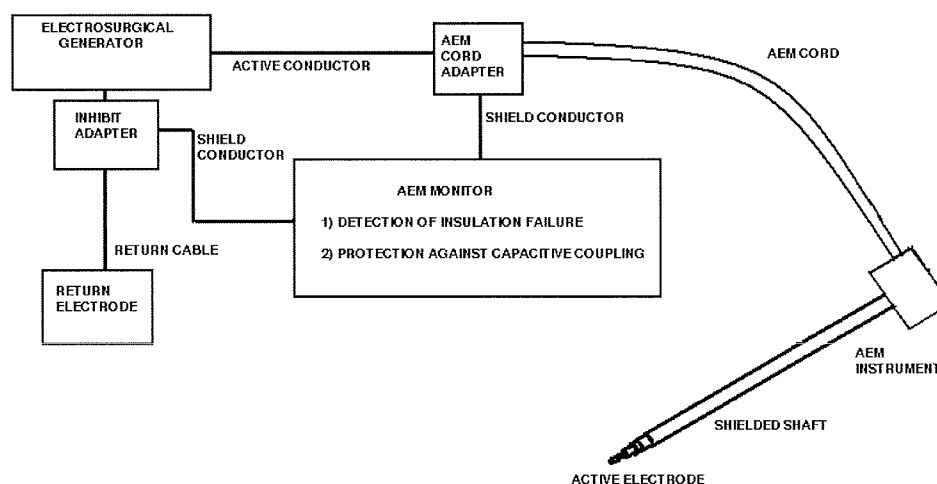
Capacitively coupled currents also have the potential for causing burns. The radio frequency energy used in electrosurgery will flow between closely spaced conductors even though there is no direct connection between them. The active electrode and a metallic cannula are closely spaced conductors, and they form a capacitor which can conduct radio frequency current. Testing has shown that 5% to 40% of the power indicated on the electrosurgical generator may be delivered from a metallic insulated trocar sheath to the patient's tissues. This amount of power is enough to cause a serious burn quickly.





The 5mm AEM Laparoscopic Instruments incorporate a layered design. AEM Instruments are shielded and monitored to prevent stray electrosurgical burns along the shaft of the instrument caused by insulation failure or capacitive coupling. The protective shield built into all AEM Instruments provides a neutral return path for capacitively coupled energy and protection from insulation failure. The shield is continuously monitored during surgery which provides continuous assurance of the integrity of the instrument.

ACTIVE ELECTRODE MONITORING SYSTEM



The AEM Monitor measures the currents flowing in the AEM integrated instruments, detects faults in the insulation, monitors the connections of the shield and the return electrode. The AEM Monitor includes an inhibit adapter which connects between the electrosurgical generator and the return electrode. When an insulation or connection fault is detected, the AEM Monitor interrupts the contact quality monitor circuit of the electrosurgical generator. In the event of an insulation fault, an alarm sounds and a visual indicator illuminates. The normal response of the generator to the contact quality circuit interruption is inhibition of radio frequency energy output.

Notice

THE PEAK OPEN CIRCUIT VOLTAGE PRODUCED BY THE ELECTROSURGICAL GENERATOR MAY BE SLIGHTLY REDUCED WHEN IT IS USED WITH THE AEM SYSTEM. NORMALLY THE VOLTAGES PRODUCED UNDER LOADED CONDITIONS ARE NOT SIGNIFICANTLY ALTERED.

Circuit Operation (Monopolar)

The Block Diagram shown on page 5 (figure 1) shows several functional blocks. Each block (shown in a dotted enclosure) will show how the subfunctions are grouped in the current implementation. The circuit descriptions of each of these blocks are described in this section.

ESM Adapter Relay

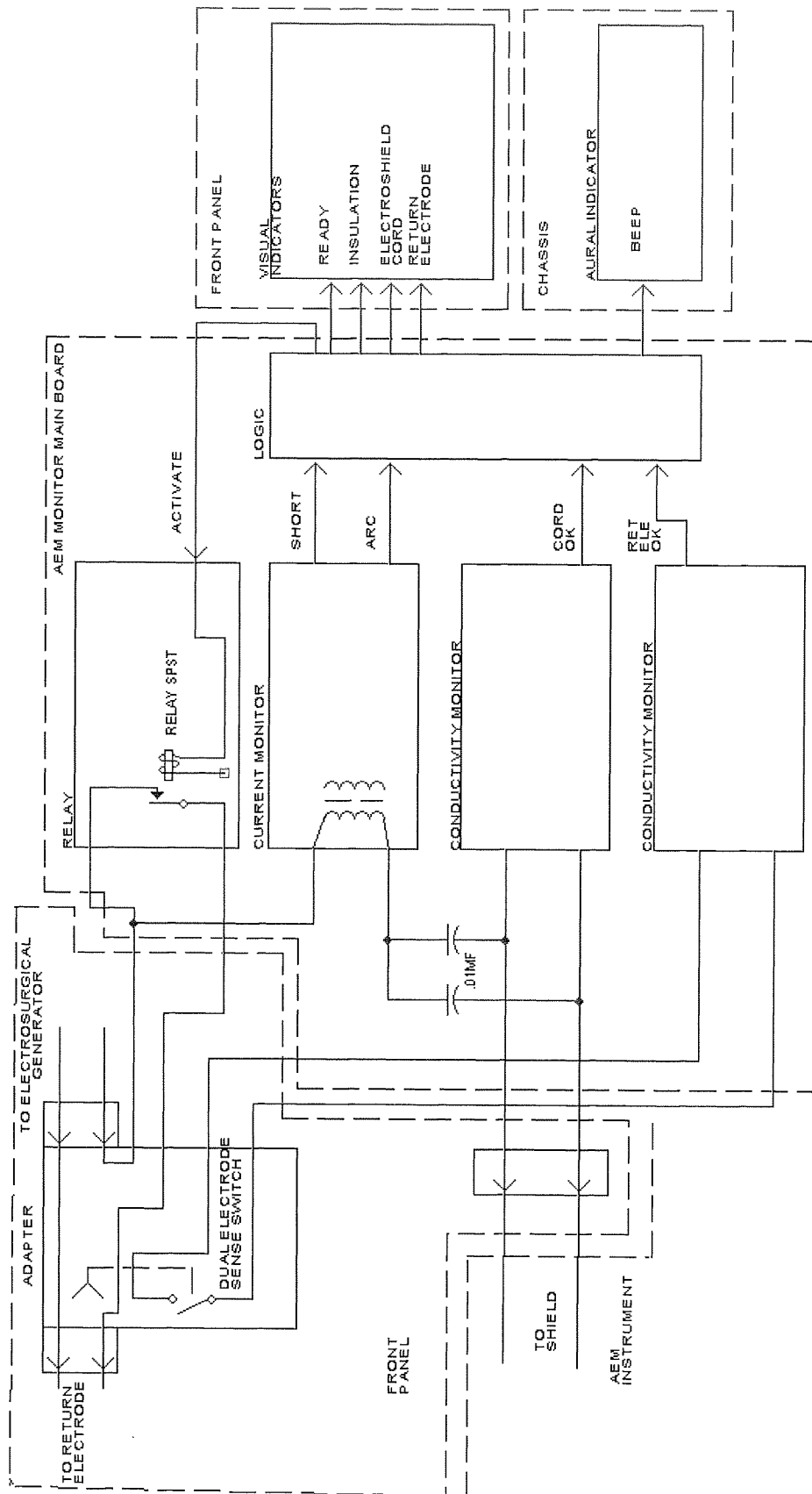
The adapter places the AEM Monitor relay electrically between the return electrode and the electrosurgical unit (ESU). The relay contact is used to place the ESU in normal or inhibit function depending on the results of the AEM Monitor measurements. When the contact is opened, the AEM Monitor signals the ESU to inhibit because the contact quality monitor within the ESU measures a high impedance. The adapter also contains a switch which is actuated by a feature on the return electrode connector. A switch activates a setup fault in the presence of the wrong type of electrode. This ensures the connection of the correct type of return electrode. A conductivity monitor reads the state of the switch.

ESM Current Monitor

To determine the status of electrode insulation, the AEM Monitor measures two aspects of the current flowing in the conductive shield which encloses the insulation. Criteria are placed on the measurements and the results of the two measurements, are passed to the logic section for alarm generation if required.

The first criterion which must be met is that the current measured over its total band width must be less than a preset value. Currents above this value generate an alert. The value at which the alarm generates varies with the waveform used, but is typically between 350 and 600 mA rms for cutting waveforms. Currents of this magnitude or higher are produced at typical control settings when the active electrode is shorted to the shield. The T2 current transformer with R14 produces a voltage signal proportional to the shield current. U8 forms a full-wave rectifier with U10 differentially amplifying the filtered result yielding a current magnitude signal. U9B then compares this magnitude with a preset value determined by R57 and R58 and the results of this comparison are input to the logic section.

The second current criterion involves a filtered component of the current centered around a frequency which is well below the principle frequency of electrosurgical waveforms. When the magnitude of this component of current exceeds a predetermined fraction of the magnitude of the wide band current, an alarm is generated. This typically happens when a spark is generated between an active conductor and the shield, and that may occur over the entire range of generator coagulation control settings. U3 forms a 3-pole filter for the current signal. U5 detects the filtered signal, with U10A amplifying it and U9A performing the comparison.



BLOCK DIAGRAM, ESM PORTION, AEM MONITOR

ESM Conductivity Monitors

The conductivity monitors sense the circuit resistance in the AEM Monitor circuit and the dual electrode sense switch circuit. When the circuit resistance is less than approximately

50 ohms the circuit outputs a positive logic level signal. When greater circuit resistance is present, the circuit outputs a low logic level signal. The circuit outputs are isolated from the inputs. The circuit diagram is given in the "ESU Interface" drawing in Section 10, Board Drawings and Schematics. Both of the conductivity monitors operate in the same way.

The monitor circuitry includes U1A and the surrounding components, and the optical isolator IS01. Resistors R8 and R10 form one leg of a bridge and R9, R72 and the external circuit resistance form the other leg of the bridge. The amplifier in U1A functions as a null detector. When the external circuit resistance is less than the null point, the amplifier output at pin 1 will be high allowing all of the current out of R1 to flow through the diode of the optical isolator. When the external circuit resistance is greater than the null point, the amplifier shunts all of the current out of R1 around the diode. When the optical isolator diode is conducting, the isolator transistor is also conducting, which pulls the output voltage to near 5 volts. When the diode is not conducting, the transistor is not conducting, causing the output voltage to be near ground. These transitions are briefly delayed to the logic input buffer (U6-7) by R74 and C34. The buffer output drives the Programmable Logic Device (PLD) logic input (U4-5). R74 and C34 also serve to suppress the effects of RF pickup as well as R72, C49, and C5.

The conductivity monitors described above are isolated from the circuit ground used by the other circuits. Consequently, the conductivity monitors must be powered by an isolated power supply. The primary side of transformer T1 is driven by a FET (Q1) whose input is connected to the system's 8 kHz, square-wave clock. The output appearing at the secondary winding of T1, is rectified by diode D2, filtered by C1 and C4, and regulated to approximately 4 volts by Zener D1.

Logic

The Logic Circuitry controls the functioning of the unit in response to sensors measuring external parameters, such as: **AEM Cord** connected, **Patient Electrode** connected, Active electrode short or arcing to Electroshield. The responses include activating: front panel indicators, audible indications, and the control relay. The Logic Circuitry is shown in the schematic, ESM, Logic drawing.

The logic is paced by the system clock whose frequency is controlled to approximately

8.2 kHz by precision RC components (R38, R39, C27) and a clock IC (U7). This primary frequency is counted down by a counter chain in U7 to form square-wave outputs of

512 Hz, 2 Hz, and 0.5 Hz. These outputs are applied to logic inputs of the PLD (U4) at pins 8, 9, and 10, respectively.

The Power-On Detector generates a 50 ms, positive logic pulse "PON" when the power has just been turned on after being off for more than 5 seconds. When the system power is off, C32 is discharged. When the system power is turned on, the juncture of C32 and R37 will be at a positive voltage nearly equal to the +5V supply, this causes the output of U6A to go positive. Then C32 will charge to the supply voltage through R37. When the voltage across C32 becomes large enough, the buffer amplifier U6A turns off and its output goes to zero. Resistor R36 along with R35 cause positive feedback to be applied so that the transitions will be quick. Diode D5 prevents the input to U6A from being damaged by negative input caused when the power is turned off, and C55 is intended to eliminate RF interference.

The functional logic is determined by the PLD in U4 (GAL6001). Logic input signals are buffered by the amplifiers in U6 to ensure proper logic levels. The logic output signals are buffered by the amplifiers in U2 to supply sufficient sink current as required by the output indicators.

The functional logic implemented by the PLD is described below. The "PON" signal causes a reset of the time counter and all internal counters and starts the Power On System Test (POST) cycle. A six-bit counter, implemented with buried flip-flops, counts the 2 Hz clock input and is used to time the various actions.

Each of the indicators is driven by a separate PLD output. During the POST cycle, all indicators are turned on to test the indicator circuitry. The **AEM Cord** indicator is controlled by the "CORDS" signal which indicates whether the cord is in place. The **Return Electrode** indicator is controlled by the "REF" signal which indicates whether the return electrode connector is plugged into the adapter. The **Insulation** indicator illuminates when either the "SHORT" or "ARC" signals are present and remains on for 30 seconds after activation. The "SHORT" signal indicates that the current being drained by the shield exceeds a predetermined threshold, and the "ARC" signal indicates that there is an arc to the shield. In addition, the meaning of the **AEM Cord** and **Insulation** indicators are changed when the unit is in a debug mode. This mode is active when the Electroshield cord is in place while the return electrode is unplugged, thus causing the **AEM Cord** indicator to illuminate when a short is detected ("SHORT" signal) and the **Insulation** indicator to illuminate when an arc is detected ("ARC" signal). The **Ready** indicator illuminates when the ESM Adapter Relay is closed.

The ESM Adapter Relay is driven by its own PLD output and it is closed when none of the fault conditions mentioned above are present and after five seconds of an **Insulation** fault. The ESM Adapter Relay is open during the POST cycle.

The beep is created by driving a speaker with a 512 Hz square wave signal that is gated by the PLD logic to cause 0.5 second beeps separated by a 0.5 second pause at the required times. Two beeps are generated at the end of the POST cycle and one beep is generated when an **Insulation** fault is detected followed by three beeps five seconds later.

Visual Indicators

The visual indicators are LEDs located on the front panel. The power **On** illuminates from the -15 V supply, the **AEM Cord**, **Return Electrode**, **Insulation**, and **Ready** indicators are powered by the +15 V supply and controlled by the Logic circuitry.

Aural Indicator

A small speaker is mounted on the rear panel of the chassis and it produces the beep for the AEM Monitor alarms and a click for the Endpoint Monitor changes.

Theory of Operation - Endpoint Monitoring System

The surgeon may use the Endpoint Monitor (a radio-frequency (RF) ammeter) to aid in determining the end point of bipolar electrosurgical desiccation.

Desiccation is a process whereby heat is dissipated in tissue, and the electrolytic fluid is driven away. As desiccation takes place the electrical impedance of the tissue and the flow of current changes. A bar-graph displays the current calibrated in tenths of an ampere. As the current changes, the frequency of clicks change.

Use the Endpoint Monitor, in conjunction with visual, tactile, temporal, and aural information observed during surgery. The surgeon must use all the information presented and interpret it with reference to experience to determine that desiccation is satisfactorily completed. Thus, it is important not to draw conclusions about the completion of desiccation from the indications of the Endpoint Monitor alone.

Circuit Operation (Bipolar)

The Block Diagram shown on page 9 (figure 2) shows several functional blocks. Each block (shown in a dotted enclosure) will show how the subfunctions are grouped in the current implementation. The circuit descriptions of each of these blocks are described in this section.

RMS to DC Converter

The ESU waveforms used vary over a wide range of shapes. Thus the heating value of the current or RMS is the signal conversion method of choice. This allows the ammeter display to read a value which is closely related to the surgical effect the surgeon is seeking. T1 in combination with R4 and R5 provide a voltage proportional to the instantaneous electrosurgical current. U1 provides a heating (root-mean-squared) conversion of this signal to U2 which amplifies and scales the signal to a level which is appropriate to drive the display. Gain calibration is inherent and controlled by the precision devices U1 and U2 in combination with 1% resistors R 7, 9, 10, 11. The offset is set by R13.

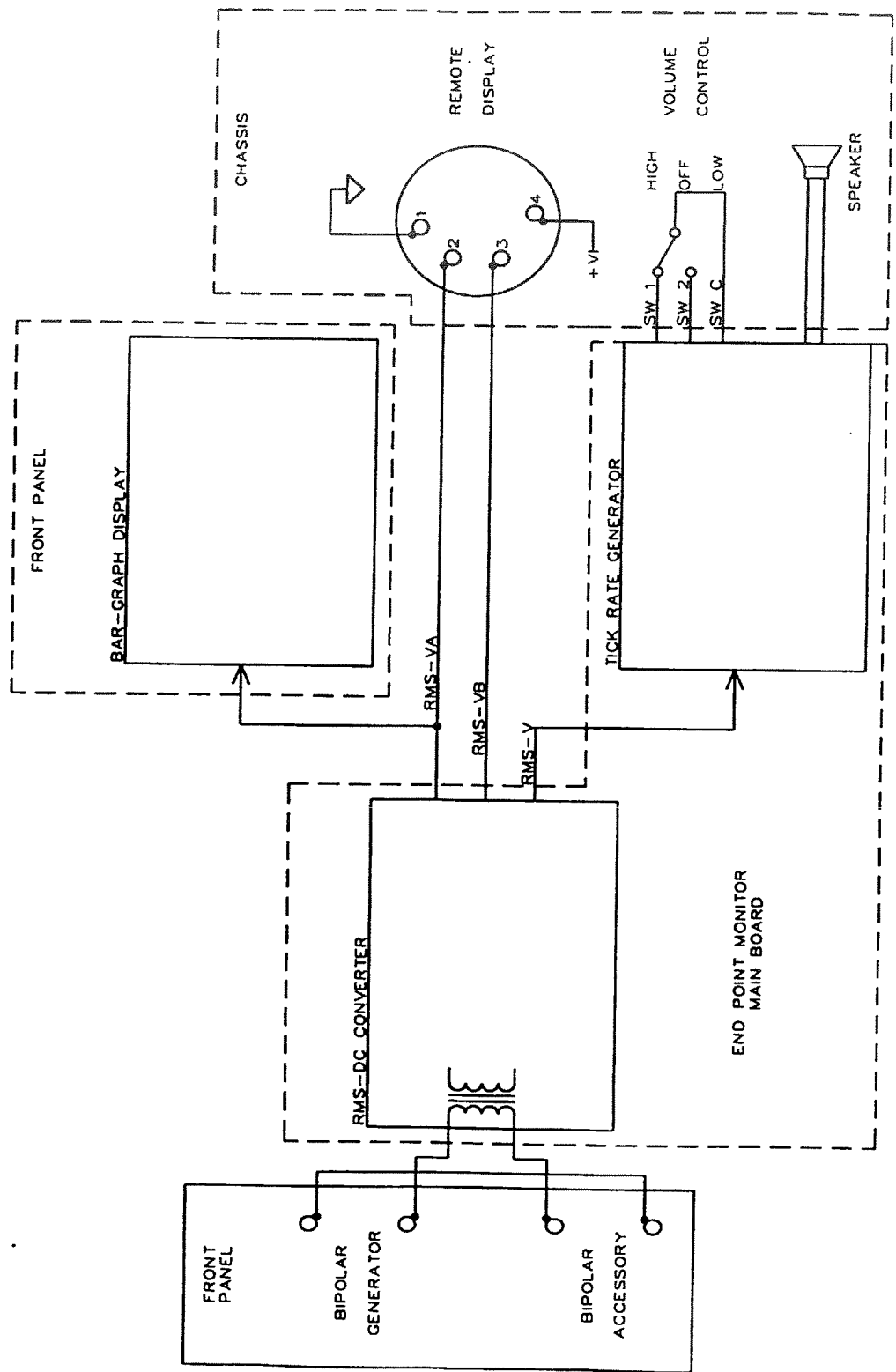


Figure 2

BLOCK DIAGRAM, EPM PORTION, AEM MONITOR

Tick Rate Generator

U2C and U4D form a current source converting the input voltage signal to a current signal. A current mirror comprised of U4C,D refers the current to the +15V supply. U3 is an oscillator whose frequency is dependant upon the charging current applied to C21. The discharge of C21 is through R24 resulting in discharge time short compared to the charge time. U4A and Q1 form an amplifier to drive the speaker from the oscillator output. The short discharge of C21 causes a "tick" to be heard from the speaker.

Bar-graph Display

LED bar-graphs U1-3 form a 30 segment display. U4-6 are a comparator array which convert an analog input to the appropriate switch closures and current source to form a bar whose length is proportional to the magnitude of the current. Offset and gain are inherent in the function of the ICs U4-6 and are accommodated by the RMS to DC convertor. Segment intensity is controlled by the values of R1, R3, and R5.